

## When Performance is Priority

Clinical Benefits of the Removal of Middle Molecules



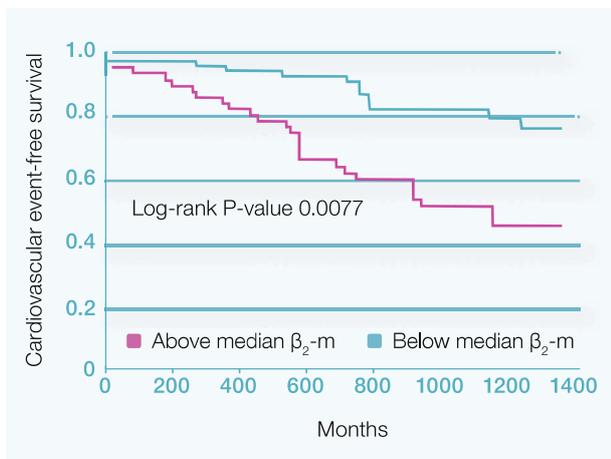
Cardioprotective Haemodialysis **SPOT**

# Protect your Patient

## Improved survival with High-Flux membranes

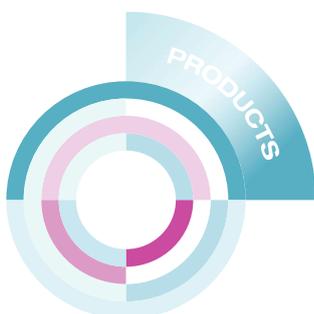
On top of traditional cardiovascular risk factors, increased middle molecule levels such as  $\beta_2$ -microglobulin ( $\beta_2$ -m) pose an additional risk for the development of cardiovascular diseases (CVD) in end stage renal disease (ESRD) patients. The European Uremic Toxin Work Group (EUTox) confirmed the power of  $\beta_2$ -m to predict overall and cardiovascular mortality and cardiovascular events in patients at different stages of CKD.<sup>1</sup>

Thus, enhanced middle molecule removal contributes towards improving long-term patient outcomes and reducing dialysis related complications.



Kaplan-Meier estimates of the probability of cardiovascular event-free survival of predialysis patients, as a function of median plasma  $\beta_2$ -m level<sup>1</sup>

(Graph adapted from original publication)

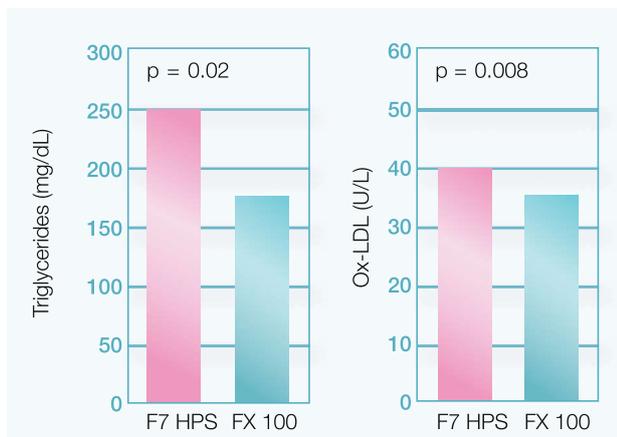


## Cardioprotective Haemodialysis

- Dyslipidaemia** – the use of High-Flux Helixone® membranes improves plasma lipid profiles,<sup>2</sup> reducing levels of LDL (low-density lipoprotein) and VLDL (very low-density lipoprotein) and increasing those of protective HDL (high-density lipoprotein). The levels of triglycerides and oxidised LDL, an indicator of oxidative stress and a specific risk factor for atherosclerosis, are also significantly reduced using Helixone® membranes.<sup>3</sup>

### SPOT on:

- Improved patient survival.<sup>1</sup>
- Reduced risk factors of atherosclerosis.<sup>3</sup>

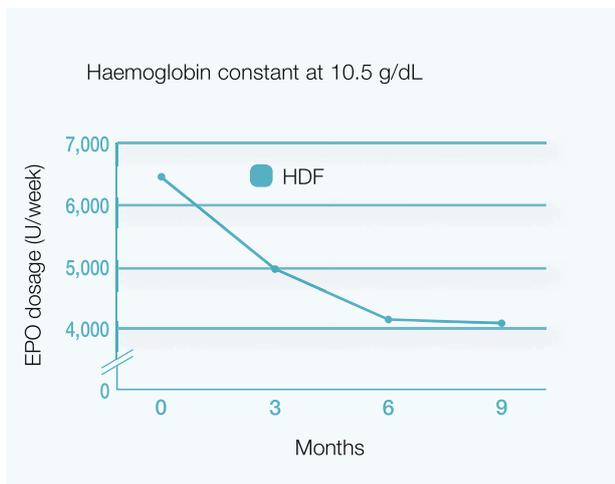


Improving plasma lipid profiles: reduction of ox-LDL and triglycerides with FX 100 dialysers<sup>3</sup>

(Graph adapted from original publication)

## Cardioprotective Haemodialysis

- **Amyloidosis** – a debilitating complication of longterm haemodialysis, amyloidosis involves the build-up of  $\beta_2$ -microglobulin. FX-class<sup>®</sup> High-Flux dialysers efficiently remove  $\beta_2$ -microglobulin and other middle molecules, reducing the risk of carpal tunnel syndrome.<sup>4,5</sup>
- **Inflammation** – specialised production processes such as INLINE steam sterilisation as well as the high endotoxin retention properties of FX-class<sup>®</sup> dialysers contribute to reducing the levels of endotoxin exposure during haemodialysis. This results in the reduced induction of inflammatory responses.<sup>2</sup>



With High-Flux membranes, it was possible to progressively reduce the EPO dose while maintaining Hb control<sup>6</sup>

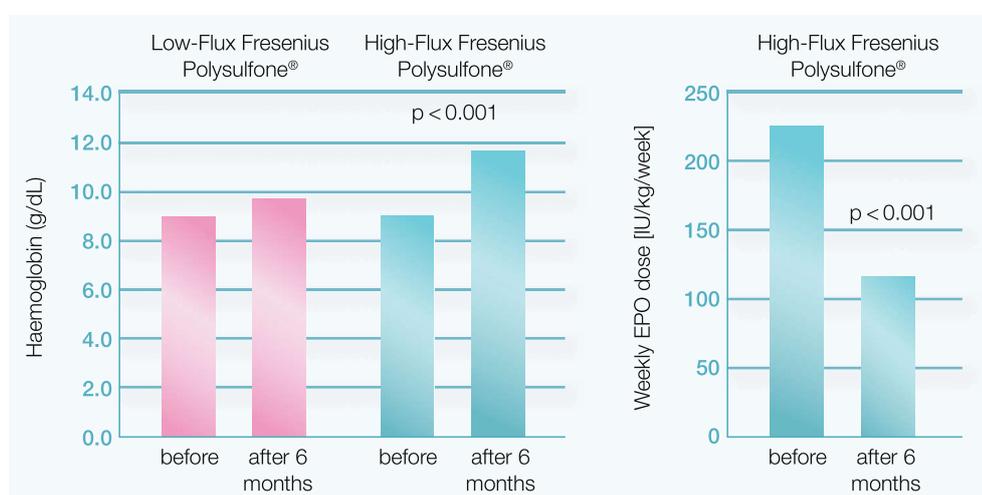
(Graph adapted from original publication)



- Anaemia management** – it was shown that High-Flux membranes improved control of anaemia in EPO hypo-responsive patients while allowing a progressive reduction in the exogenous EPO dose by 25 to 45 %.<sup>7</sup> Hence, High-Flux membranes offer the potential to reduce EPO costs.

SPOT on:

- Improved anaemia control.<sup>6,7</sup>
- Reduced inflammation.<sup>2</sup>
- Reduced risk of CVD due to minimising the risk factors.



Recovery of haemoglobin (Hb) levels was significantly better after 6 months for patients treated with High-Flux vs Low-Flux membranes. Further, in this patient group the mean EPO dose was significantly lower.<sup>7</sup> (Graph adapted from original publication)

The FX CorDiax allows the enhanced removal of middle molecules which, together with other factors, contributes towards improved survival.

1 Liabeuf S. et al., *Kidney International* (2012) 82, 1297.  
 2 Merello Godino J. I. et al., *Int J Artif Organs* (2002); 25(11): 1049-1060.  
 3 Wanner C. et al., *JASN* (2002); 13 (SU-P0645): 600A.  
 4 Ahrenholz P. G. et al., *Clinical Nephrology* (2004); 62: 21-28.  
 5 Koda Y. et al., *Kidney Int* (1997); 52: 1096-1101.  
 6 Bonforte G. et al., *Blood Purif* (2002); 20: 357-363.  
 7 Ayli D. et al., *J Nephrol* (2004); 17: 701-706.

## Performance Data

## Atitikimas 7,8 pirkimo dalims

Sieving coefficients of FX CorDiax High-Flux Dialysers and Haemodia filters	Molecular weight (Dalton)						
Albumin	66,500	< 0.001					
Myoglobin	17,053	0.5					
$\beta_2$ -microglobulin	11,731	0.9					
Inulin	5,200	1					
Membrane material		Helixone® plus					
Sterilisation method		INLINE steam					
Housing material		Polypropylene					
Potting compound		Polyurethane					
Units per box		Atitikimas 7 pirkimo daliai			Atitikimas 8 pirkimo daliai		
<b>FX CorDiax High-Flux Dialysers</b>		<b>FX CorDiax 40</b>	<b>FX CorDiax 50</b>	<b>FX CorDiax 60</b>	<b>FX CorDiax 80</b>	<b>FX CorDiax 100</b>	<b>FX CorDiax 120</b>
<b>Clearance (<math>Q_b = 300</math> mL/min)</b>							
Cytochrome c	12,230	48 *	76	96	111	125	136
Inulin	5,200	56 *	88	116	127	144	149
Vitamin B <sub>12</sub>	1,355	96 *	144	175	190	207	213
Phosphate	132	142 *	215	237	248	258	262
Creatinine	113	155 *	229	252	261	272	274
Urea	60	175 *	255	271	280	283	284
<b>Clearance (<math>Q_b = 400</math> mL/min)</b>							
Cytochrome c	12,230	–	–	100	117	133	145
Inulin	5,200	–	–	122	135	154	160
Vitamin B <sub>12</sub>	1,355	–	–	191	209	229	237
Phosphate	132	–	–	270	285	299	305
Creatinine	113	–	–	290	303	321	325
Urea	60	–	–	319	336	341	343
*Clearance ( $Q_b = 200$ mL/min)							
Ultrafiltration coeff. (mL/h x mmHg)		21	33	47	64	74	87
<i>In vitro performance: <math>Q_b = 500</math> mL/min, <math>Q_f = 0</math> mL/min, <math>T = 37^\circ\text{C}</math> (EN 1283). Sieving coefficients: human plasma, <math>Q_b</math> max, <math>Q_f = 0.2 \times Q_b</math> max (EN1283). Ultrafiltration coefficients: human blood (Hct 32%, protein content 6%).</i>							
Effective surface (m <sup>2</sup> )		0.6	1.0	1.4	1.8	2.2	2.5
K <sub>0</sub> A Urea		547	886	1,164	1,429	1,545	1,584
Priming volume (mL)		32	53	74	95	116	132
Article number		F00001588	F00001589	F00001590	F00001591	F00001592	F00002384
<b>FX CorDiax Haemodia filters</b>		<b>FX CorDiax 600</b>	<b>FX CorDiax 800</b>	<b>FX CorDiax 1000</b>			
<b>Clearance (<math>Q_b = 300</math> mL/min, <math>Q_f = 75</math> mL/min)</b>							
Cytochrome c	12,230	131	141	151			
Inulin	5,200	144	156	166			
Vitamin B <sub>12</sub>	1,355	204	217	225			
Phosphate	132	257	267	271			
Creatinine	113	271	277	280			
Urea	60	285	291	292			
<b>Clearance (<math>Q_b = 400</math> mL/min, <math>Q_f = 100</math> mL/min)</b>							
Cytochrome c	12,230	149	160	172			
Inulin	5,200	166	178	190			
Vitamin B <sub>12</sub>	1,355	235	251	262			
Phosphate	132	307	321	328			
Creatinine	113	327	339	343			
Urea	60	354	365	367			
Ultrafiltration coeff. (mL/h x mmHg)		46	62	76			
<i>In vitro performance: <math>Q_b = 500</math> mL/min, <math>T = 37^\circ\text{C}</math> (EN 1283). Sieving coefficients: human plasma, <math>Q_b</math> max, <math>Q_f = 0.2 \times Q_b</math> max (EN1283). Ultrafiltration coefficients: human blood (Hct 32%, protein content 6%).</i>							
Effective surface (m <sup>2</sup> )		1.6	2.0	2.3			
K <sub>0</sub> A Urea		1,148	1,365	1,421			
Priming volume (mL)		95	115	136			
Article number		F00001593	F00001594	F00001595			

FX CorDiax

Atitikimas 7, 8 pirkimo dalims

Sukurti dializei. Suprojektuoti kardioprotekcijai

**Designed to dialyze. Built for cardioprotection.**

- Efficient middle molecule removal
- **INLINE steam sterilized** Sterilizacija vandens garais
- Low rinsing volume

#### DISCLAIMER

Not all products and services are cleared or available for sale in all EU countries. Check your [country web site](#) for details.

Key features **Technology** Performance Data Studies

#### Advances in fiber design allow for better removal of uremic toxins

- The fiber support region underneath the inner surface has been "opened up", optimizing porosity and therefore also the convective filtration ("flushing") of larger uremic toxins such as  $\beta_2$ -microglobulin ( $\approx 11,800$  Da) or myoglobin ( $\approx 17,000$  Da)
- At the same time the size of the pores of the inner surface area was not increased to avoid flushing of albumin

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#### Superior by design

Several state-of-the-art technologies have been combined to create the distinctive, functional features of FX-class dialyzers, which are refined and optimized for performance and handling:

- Design of dialyzer housing and fiber bundle for more uniform dialysate flow
- Refined blood inlet port for improved hemodynamics

Medžiagų ir gamybos technologijos leidė patobulinti heliksono membranos sienelės struktūrą FX CorDiax dializatoriams.

Advances in material and production technologies have permitted improvements in the wall structure of the Helixoneplus membrane of the FX CorDiax.

- More porous membrane wall for higher clearance of middle molecules
- Padidinto poringumo membrana dėl geresnio vidutinių molekulių šalinimo

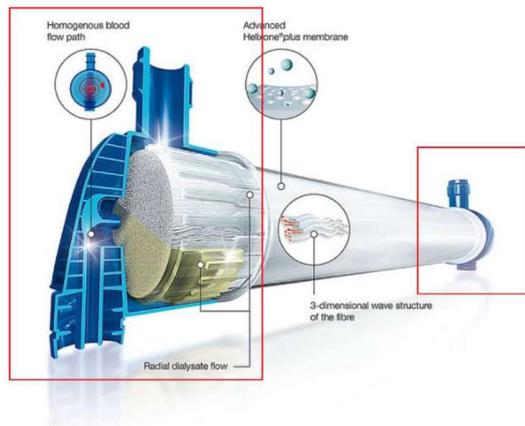
Atitikimas 7, 8 pirkimo dalims

Homogenous blood flow path

Advanced HelixonePlus membrane



Šoninis kraujo įleidimo prievadas.



FX-class dialyzers design

Atitikimas 7, 8 pirkimo dalims

<p><b>Optimized dialysate flow</b></p>	<p>The 3-dimensional microwave structure of the fiber ensures niform radial dialysate flow around each fiber within the bundle by preventing fluid channeling, thereby enhancing clearance values and improving the overall performance of the dialyzer.</p>
<p><b>Better hemodynamics</b></p>	<p>The lateral blood-inlet port ensures more homogenous blood flow in the dialyzer header, preventing stagnation zones. The design essentially minimizes the risk of kinking, contributing to improved safety.</p>
<p><b>Enhanced convection</b></p>	<p>The more open structure of the Helixoneplus membrane support region serves to reduce diffusion resistance and increases convective filtration. This facilitates clearance of a broad range of uremic toxins, especially the middle molecules.</p>
<p><b>Kind to the environment</b></p>	<p>Advanced design goes beyond direct functionality, it also has to be easy on the environment. FX-class dialyzers weigh half as much as dialyzers with polycarbonate housing, and at the same time use ecologically friendly plastics. This means a lower carbon-footprint as a result of fewer materials, less packaging, less fuel for transport and cleaner waste management.</p>